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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,129	06/28/2002	Jussi Kauhanen	2630-114	1660
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6449 7590 04/15/2004

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WASHINGTON, DC 20005

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

89.

# Office Action Summary

Application No.

10/069,129

Applicant(s)

KAUHANEN ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1-9 are pending.

The amendment to the specification and claims 1, 2, 3, 4, and 7 filed on 2/22/02 is acknowledged and entered.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 2, drawn to a method of diagnosing a person's susceptibility for having a risk for the development of alcoholism, wherein the method uses a position 7 allele specific oligonucleotide probe.

Group II, claim(s) 1 and 3, drawn to a method of diagnosing a person's susceptibility for having a risk for the development of alcoholism, wherein the method uses an antibody capable of binding the signal peptide part of human preproNPY.

Group III, claim(s) 1 and 3, drawn to a method of diagnosing a person's susceptibility for having a risk for the development of alcoholism, wherein the method uses an antibody capable of binding any cleavage product of said human preproNPY other than the signal peptide of human preproNPY.

Group IV, claim(s) 4, 5, and 6, drawn to a method of a treating a person diagnosed for having a risk for the development of alcoholism, comprising administering to said person an agent counteracting the influence of the mutated gene, wherein said agent modulates gene expression of the normal NPY gene.

Group V, claim(s) 4, 5, 6, and 7, drawn to a method of a treating a person diagnosed for having a risk for the development of alcoholism, comprising administering to said person an agent counteracting the influence of the mutated gene, wherein said agent modulates gene expression of the mutated NPY gene.

Group VI, claims 8 and 9, drawn to a method of screening pharmaceuticals useful in the prevention or treatment of alcoholism, by using a transgenic non-human animal whose genome comprises a nucleotide sequence encoding prepro-neuropeptide Y (preproNPY) mature human NPY peptide, wherein position 7 of the signal peptide is leucine.

Group VII, claims 8 and 9, drawn to a method of screening pharmaceuticals useful in the prevention or treatment of alcoholism, by using a transgenic non-human animal whose genome comprises a nucleotide sequence encoding prepro-neuropeptide Y (preproNPY) mature human NPY peptide, wherein the leucine amino acid in position 7 of the signal peptide of said preproNPY has been replaced by proline.

The inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

The special technical feature of Group I is considered to be a method of diagnosing a risk of a person developing alcoholism using a position 7 allele specific oligonucleotide probe.

The special technical feature of Group II is considered to be a method of diagnosing a risk of a person developing alcoholism using an antibody capable of binding the signal peptide part of said human preproNPY.

The special technical feature of Group III is considered to be a method of diagnosing a risk of a person developing alcoholism using an antibody capable of binding any cleavage product other than the signal peptide of said human preproNPY.

The special technical feature of Group IV is considered to be a method of treating a person diagnosed for having a risk of developing alcoholism using an agent that modulates gene expression of the normal NPY gene.

The special technical feature of Group V is considered to be a method of treating a person diagnosed for having a risk of developing alcoholism using an agent that modulates gene expression of the mutated NPY gene.

The special technical feature of Group VI is considered to be a method of screening pharmaceuticals useful in the prevention or treatment of alcoholism, by using a transgenic non-human animal whose genome comprises a nucleotide sequence encoding a mature normal human NPY peptide.

The special technical feature of Group VII is considered to be a method of screening pharmaceuticals useful in the prevention or treatment of alcoholism, by using a transgenic non-human animal whose genome comprises a nucleotide sequence encoding a mutated human NPY peptide.

Accordingly, Groups I-VII are not so linked by the same or a corresponding technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

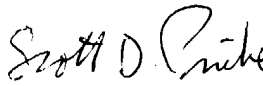
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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER